

REMARKS

The present response is intended to be fully responsive to all points of objections and rejections raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested. Applicant asserts that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 66-104, 108 and 109 have been rejected. Claims 66-67, 78-82, 89 and 95-96 have been amended.

Claims 101 and 108-109 have been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicant reserves all rights in these claims to file divisional and/or continuation patent applications.

New claims 120-122 have been added in order to further define what the Applicant considers to be the invention. The amendments to the claims are fully supported by the original claims and specification. For example, support for new claim 122 can be found in the original specification, for example on page 5, paragraph 0070. No new matter has been added by the amendments made herein. Entry of the amendments at this time is therefore respectfully requested.

Claim rejections - 35 USC § 102

Claims 108 and 109 were rejected under 35 U.S.C. 102(b) as being anticipated by Mault (USP #5,179,958). Claims 108 and 109 are cancelled herein. Thus, Applicant respectfully requests that this rejection be withdrawn as the rejection is now moot.

Claim rejections - 35 USC § 103(a)

Claims 66-74, 76-79, 84-89, 91, 95, 96, 98-102, and 104 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,797,885) in view of Mottram (USP #6,488,635). Applicant respectfully traverses.

Lemelson and Mottram, alone or in combination, do not teach or suggest the invention as presently claimed in independent claim 66. The presently claimed invention is

directed to: a system for collecting a plurality of samples of breath of a subject comprising, *inter alia*:

"a breath conduit adapted to convey exhaled breath from the subject;

a carbon dioxide **sensor for determining carbon dioxide level** in said exhaled breath, wherein said sensor is adapted to provide a signal indicative of said carbon dioxide level in said exhaled breath, wherein said **signal is adapted to trigger the commencement of collection of samples of at least part of said exhaled breath**; a plurality of sample containers for collection of said plurality of samples..." as required in amended claim 66.

Neither Lemelson nor Mottram teach or suggest these required elements of the invention, alone or in combination. Accordingly, they cannot make obvious Applicant's invention as claimed. Thus, Applicant respectfully asserts that amended independent claim 66 is allowable.

Lemelson and Mottram, also do not teach or suggest, alone or in combination, the invention as presently claimed in independent claim 95. Specifically, Lemelson and Mottram do not teach or suggest: a system for collecting a plurality of samples of breath of a subject comprising *inter alia*:

"a **capnographic analyzer** for determining carbon dioxide concentration in said exhaled breaths of the subject;

a controller adapted to **receive input at least from said capnographic analyzer**;

a sample distributor which is adapted to direct different predetermined samples of said exhaled breaths to different ones of said plurality of sample containers, according to said controller; and

a valving system adapted to **select at least part of one of said exhaled breaths** to said sample distributor according to said **capnographic analyzer**."

Applicant agrees, as pointed out in the Office Action, that neither Lemelson, nor Mottram disclose a capnographic analyzer as currently claimed. Applicant further asserts that none of the prior art cited teach or suggest, "a valving system adapted to select **at least part of one of said exhaled breaths to said sample distributor according to said capnographic analyzer**" alone or combined either. Without these claimed invention elements, the particular selected samples could not be further analyzed at a later stage. These

claim elements provide several significant differences between the prior art devices and the presently claimed invention.

To further assist the Examiner in understanding the differences between Applicant's invention and the prior art, Applicant wishes to draw the Examiner's attention to several advantages that the present invention has over the prior art. These advantages were not taught or suggested by the prior art and neither were the problems resolved by the invention identified, thus, they could not be resolved. The present invention allows for effective collection of exhaled breath samples without the need of the subject's cooperation. The carbon dioxide sensor is adapted to detect the carbon dioxide level in samples/air flow pumped into the system and determine which are the relevant parts of the exhaled breath and allows for testing of only the relevant samples, even if the subject does not cooperate, providing for a much more reliable and effective system. The cited prior art does not teach or suggest each of the elements of claim 95 alone or in combination, and therefore would not have the advantages of the presently claimed invention.

Accordingly, amended independent claim 95 is not obvious over the prior art, providing specific functional advantage over the prior art devices. Thus, Applicant respectfully requests that this rejection be withdrawn.

Claims 67-74, 76-79, 84-89, 91, 96, 98-102, and 104 depend, directly or indirectly, from claims 66 and 95, and therefore include all the limitations of claim 66 or 95. Therefore, these dependent claims are likewise allowable for all of the same reasons set forth above.

Claims 75 and 97 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Mottram (USP #6,488,635) as applied to claims 66 and 95 above, and further in view of Dietz (USP #5,005,571).

Claims 75 and 97 depend from, directly or indirectly, amended claims 66 and 95 and therefore include all the limitations of those claims. Therefore, Applicant respectfully asserts that claims 75 and 97 are likewise allowable.

Claims 80-82 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Mottram et al. (USP #5,797,885) as applied to claim 78 above, and further in view of Hoberman (USP #5,159,934).

Amended claims 80-82 depend from amended claim 66 and are also therefore patentable for the same reasons set forth above.

As pointed out in the Office Action "...neither Lemelson nor Mottram specifically disclose a capnographic analyzer." There is no motivation to modify the devices in Lemelson or Mottram either. Thus, Hoberman fails to remedy the deficiencies of Lemelson and Mottram. None of these references teach one how to combine a carbon dioxide sensor with a system such as shown in Lemelson or Mottram. Furthermore, none of the references teach why such a modification should be made. Applicant respectfully directs the Examiner's attention to various unexpected benefits that they were the first to teach and were not identified in the prior art.

New claims 120 and 121 and as shown in the specification, for example, point to some of the unexpected benefits Applicant's device provides over the prior art devices: ability of determining effectiveness of a drug (Page 6, Paragraph 0075), determining bacterial overgrowth (Page 6, Paragraph 0075), determining volatile organic compounds (VOC) content (Page 7, Paragraph 0085), determining a volume of a labeled molecule exhaled (Page 8, Paragraph 0086), determining ratio of isotope concentrations (Page 8, Paragraph 0086), determining liver function (Page 8, Paragraph 0086) and determining pancreatic function (Page 8, Paragraph 0086). These unexpected benefits provide further evidence that the presently claimed invention is non-obvious over the prior art and is worthy of patent protection, as Applicant has provided a useful advancement over the prior art that provide many advantages, while more effectively collecting a plurality of breath samples.

Accordingly, Applicant asserts that claims 80-82 are allowable and respectfully requests that this rejection be withdrawn.

Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885), Mottram et al. (USP #5,797,885), and Hoberman (USP #5,159,934) as applied to claim 82 above, and in further view of Casparie et al. (USP #5,069,220). Claim 83 depends from amended claim 66. Therefore, Applicant respectfully asserts that claim 83 is likewise allowable for all the reasons set forth above.

Furthermore, as pointed out in the Office Action, Lemelson, Mottram, and Hoberman do not disclose a system where breath is collected when CO₂ concentration is at the plateau value of its waveform, such that alveolar air is sampled. Casparie fails to remedy the deficiencies for several reasons.

First, Applicant asserts that Lemelson, Mottram, Hoberman and Casparie, alone or in combination, do not teach or suggest: a system wherein the collection of samples of at least part of said exhaled breath is **triggered by the carbon dioxide level** of the breath or part of breath. Casparie teaches the use of exhaled breath when carbon dioxide concentration reaches a plateau level (col 1, lines 21-23) for the purpose of most accurate determination of **blood gas concentration**.

Second, there is no motivation to combine the references as suggested in the Office Action. The Office Action fails to show where in Casparie there exists a teaching to combine or a teaching of how to combine. There is no teaching in any of the cited art of collecting at least part of said breath when said carbon dioxide concentration of said breath is at the plateau value of its waveform, such that alveolar air is sampled, with a system such as shown in Lemmelson, Mottram and/or Hoberman. Without some teaching or suggesting to combine, with some expectation of success, the cited prior art cannot make obvious the presently claimed invention. Accordingly, Applicant respectfully requests that this rejection be withdrawn as well.

Claims 90 and 103 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Mottram et al. (USP #5,797,885), as applied to claims 66 and 95 above, and further in view of Opekun, Jr. et al. (USP #5,140,993).

Claim 90 depends from independent claim 66 and claim 103 depends from independent claim 95. Therefore, each of these claims includes all the limitations of the claim from which it depends and is allowable for all of the same reasons, as discussed above. Thus, Applicant respectfully requests that this rejection be withdrawn as well.

Claims 92-94 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885), Mottram et al. (USP #5,797,885), and Hoberman (USP #5,159,934) as applied to claim 80 above, and further in view of Daniels et al. (USP #6,099,481).

Claims 92-94 depend indirectly from amended claim 66 and therefore include all the limitations, as discussed above. Therefore, Applicant respectfully asserts that claims 92-94 are likewise allowable and this rejection should be withdrawn.

Furthermore, new claim 122 is likewise patentable over the prior art. For example, none of the prior art cited by the Examiner teach or suggest, alone or in combination, "a system for collecting a plurality of samples of breath of a subject comprising, inner

alia: breath conduit adapted to convey exhaled breath from the subject; a carbon dioxide **sensor for determining carbon dioxide level** in said exhaled breath, wherein said sensor is adapted to provide a signal indicative of said carbon dioxide level in said exhaled breath, wherein **said signal is adapted to trigger the commencement of collection of samples of at least part of said exhaled breath**; a plurality of sample containers for collection of said plurality of samples... and further comprising a pump adapted to facilitate the collection of the breath sample from the subject by means of its suction effect, and its continued motion through the sample distributor" as specifically required in new claim 122.

As further evidence of the uniqueness of Applicant's invention, Applicant wishes to draw the Examiner's attention to certain additional distinctions that further demonstrate the uniqueness of Applicant's invention and benefits over the prior art. First, the presently claimed invention specifically recites and requires a pump that allows for the continuous collection of exhaled breath. This makes it possible for the presently claimed system to collect exhaled breath without the need of the subject's cooperation. There is no need to tell or force the subject to blow or exhale. Thus, unlike the prior art, not just exhaled breaths are collected and introduced into the system, but instead a constant flow of air is taken into the system. The carbon dioxide sensor of the invention is designed to detect the carbon dioxide level in samples/air flow pumped into the system. Thus, while the system is taking in air continuously it is now able to determine **which air samples are the relevant parts of the exhaled breath** instead of requiring that all the continuous air be sampled and stored. Without the claimed invention elements, the particular selected samples could not be further analyzed at a later stage and, like the prior art systems, it would require the cooperation of the subject.

These differences and advantages were not taught or suggested by the prior art, providing further evidence of non-obviousness. Furthermore, the problems resolved by the invention were also not identified or discussed, thus, they could not be resolved. The present invention allows for effective collection of exhaled breath samples without the need of the subject's cooperation. The carbon dioxide sensor is adapted to detect the carbon dioxide level in samples/air flow pumped into the system and determine which are the relevant parts of the exhaled breath and allows for testing of only the relevant samples even if the subject's cooperation, providing for a much more reliable and effective system.

AMENDMENT IN RESPONSE TO OFFICE ACTION
Title: "Portable Breath Collection System for Use in Breath Tests"
U.S. Serial No. 10/506,872

In view of the above, Applicant respectfully requests that the claims be favorably reconsidered and an allowance be timely issued.

Should the Examiner have any questions or comments as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Respectfully submitted,

August 4, 2009
Date

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